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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m4924n

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

Certified Mail
Return Receipt Requested

November 28, 2000

W/L Number: 09 - 01

Nitaya Chitakkol. M.D.
Chief of Radiology
Hubert H. Humphrey Comprehensive Health Center
5850 South Main Street
Los Angeles, CA 90003

Inspection ID: 1963290005
CFN: 20-30;239
FEI: 1000519419

Dear Dr. Chitakkol:

We are writing to you because on October 30, 2000, your facility was inspected by a representative of the State of California, acting in behalf of the U. S. Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed Level 2, repeated Level 2, and repeated Level 3 violative findings at your facility. These findings were listed on the MQSA Facility Inspection Report provided to you at the close of the inspection. These findings are:

- Level 2: There is no written procedure for infection control. This is a REPEAT violation.

- Level 2: The measured fog density is equal to 0.11 for the darkroom in the mammography section. This is a REPEAT violation.

- Level 2: There is no written procedure for handling consumer complaints.

- Level 3: The QA program is inadequate in that there are missing and/or incomplete documents as it pertains to personnel responsibilities. This is a REPEAT violation.

These problems are presented to you because they identify a failure to meet significant MQSA requirements.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent serious violations of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or

each day of failure to substantially comply with, MQSA Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office, in writing, within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations; and

- please provide sample records that demonstrate proper record keeping procedures if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Your response should also specifically address the repeat violations which were not corrected from the previous inspection and why they were not corrected prior to the inspection of October 30, 2000.

Please submit your response to:

Mr. Thomas Sawyer
Director, Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd.; suite #300
Irvine, CA 92612-2445
Phone: (949) 798-7600

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact [redacted] (MQSA Auditor) at telephone number (949) 798-[redacted].

Sincerely yours,

Alonza E. Cruse
District Director